

REMARKS

Claims 1-21 were pending in this application. With entry of this response, Applicants have cancelled claims 20-21, as being directed to non-elected subject matter; and amended claims 1 and 16, as indicated above. Applicants respectfully request reconsideration of the claims as amended and in view of the following remarks.

35 U.S.C. § 112, Second Paragraph Rejection

Claims 16-19 were rejected for allegedly being indefinite. According to the Examiner, “shoots” in claim 16 lacks antecedent basis. Applicants have amended the claims and request that the rejections be withdrawn.

35 U.S.C. § 102(b) rejection

Claims 1-11, 13-14, and 16-19 stand rejected under 35 USC § 102(b) as being anticipated by Martinell et al (6,384,301). This rejection is respectfully traversed in view of the following claim amendments and remarks. According to the Examiner, the presently claimed step of “assaying the roots for the presence of the nucleic acid sequence” encompasses the growing the roots in the presence of a selective agent (e.g., in the soil). Applicants have amended the claims to clarify the claimed invention. The assay step noted by the Examiner now includes a step for excising or removing a portion of root tissue, and then performing the assay on that root tissue to determine if the tissue has been transformed. The ‘301 patent describes methods of selecting for transformed roots, but does not teach or suggest the presently claimed method. As all of the elements of the present claims are not described in the cited prior art, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. § 103(a) rejections

Claims 1-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Martinell et al (6,384,301) taken with U.S. 5,994,624. The ‘301 patent describes a method of transforming dicots such as soybean. Positive transformants are selected on a selection agent, such as glyphosate. Selection can be done at various stages of regeneration. Transmission of the nucleic acid of interest can also be confirmed by testing leaf tissue for the presence of the inserted

nucleic acid sequence. Positive leaf tissue is indicative of transformed tissue that can then be grown to produce progeny seed. However, the inventors found that positive results in the leaf tissue did not always correlate with germline transmission of the inserted nucleic acid (i.e., the sequence can be lost in progeny plants and seeds). This results in wasted of resources and time as plants are carried forward that do not give rise to transgenic progeny. Recognizing this problem, the present inventors discovered that transformation of root tissue correlated closely with germline transmission. Thus, by identifying the presence of the gene in the root tissue itself, a higher confidence level is obtained that the progeny will receive the nucleic acid through germline transmission. For example, in paragraph [0156], the inventors teach that analysis of R1 plants from multiple constructs indicated 75-100% correlation with plants rooting on glyphosate and germline transformation. Accordingly, the presently claimed invention overcomes the deficiencies in the prior art in a novel and unobvious way.

With that background, the present rejection may be considered in its proper context. According to the Examiner, the '301 patent describes all of the elements of the claims, but does not teach a PCR or Southern blot assay on root tissue. Instead, '301 describes assays using leaf tissue. To account for this deficiency, the Examiner relies on the '624 patent ("Trollinder"), which teaches a method of injecting Agro suspensions into floral tissue of cotton. After injection, Trollinder reports that progeny seeds were allowed to germinate in the presence of Kanamycin. Successfully germinated seeds were then grown to plantlets, and the leaf tissue was assayed for GUS and NPTII activity to confirm the presence of the selectable marker.

This rejection is respectfully traversed to the extent it continues to apply to the presently amended claims. As the Patent Office is well aware, the criterion for a determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that the claimed invention should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art. In re Dow Chemical, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988); Burlington Industries v Quigg, 3 USPQ 2d 1436, 1438 (Fed. Cir. 1987); In re Hedges, 228 USPQ 685, 687 (Fed. Cir. 1987); Orthopedic Equipment Company v United States, 217 USPQ 193, 200 (Fed. Cir. 1983); and In re Rinehart, 189 USPQ 143, 148 (CCPA 1976). Both the suggestion and the expectation of success must be founded in the prior art, not in the applicants' disclosure. Dow Chemical, 5 USPQ 2d at 1531. Moreover, in order for a combination of references to render an

invention obvious, it must be obvious that their teachings can be combined. In re Avery, 186 USPQ 161 (CCPA 1975). In other words, obviousness cannot be established by combining the teachings of the prior art to produce a claimed invention, absent some teaching, suggestion or incentive supporting the combination. In re Geiger, 2 USPQ 2d 1276 (Fed. Cir. 1987); In re Fine, 5 USPQ 2d 1596 (Fed. Cir. 1988). The mere fact that references can be combined does not render the resulting combination obvious unless the prior art also suggests the desirability of a combination and merely indicating that isolated elements recited in the claims are known is not a sufficient basis for concluding that the combination of claimed elements would have been obvious. ACS Hospital Systems, Inc. v Montefiore Hospital, 221 USPQ 929 (Fed. Cir. 1984); Ex Parte Hiyamizu, 10 USPQ 2d 1393 (Bd. Pat. App. & Int. 1988).

Each of the claims of the present invention are nonobvious because there is no teaching, suggestion or incentive supporting the combination of references cited by the Patent Office. In particular, there is no teaching or suggestion that would motivate the skilled artisan to use the leaf assays described by the '301 patent in combination with the cotton floral transformation system and leaf assays in '624. In fact, it is only through the use of improper hindsight analysis using the teachings in this application that the Patent Office is able to propose this combination. The Patent Office has combined the disparate teachings of the cited references to reach a conclusion of obviousness absent any teaching, suggestion or incentive which would have led one of ordinary skill in the art to combine the relevant teachings of the references with a reasonable expectation of success. None of the cited references provide a reasonable expectation of success for the successful plastid transformation of a non-tobacco solanaceous species, particularly potato. Moreover, even if the cited prior art could be combined, the resulting combination fails to teach or suggest the presently amended claims. In particular, the teachings in both references concerning leaf assays and selection on glyphosate or KAN do not teach or suggest the root assay system claimed by Applicants. In the absence of any reason to combine the references, the Patent Office has failed to establish a *prima facie* case of obviousness to support a §103 rejection and the rejection should be withdrawn.

Double Patenting Rejection

The Examiner provisionally rejected claims 1-9 and 13-14 under the judicially created doctrine of obviousness-type double patenting over claims 1-10 and 13 of U.S. 6,384,301. According to the Examiner, the claims are not patentably distinct. In view of the claim amendments and remarks relating to obviousness and the '301 patent, above, Applicants respectfully request that this rejection be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration on the merits of the application as a whole. The Examiner is encouraged to call the undersigned should any further action be required for allowance.

Respectfully submitted,



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